REMARKS

Claims 5-9, 11, 14, 15, 18, 25, 37-40, and 42-47 are pending in the application. Claims 11, 43, and 44 were withdrawn from consideration, leaving claims 5-9, 14, 15, 18, 25, 37-40, 42, and 45-47 subject to examination. Claims 25, 37-40, 42, and 45-47 were rejected under 35 U.S.C. § 112, first paragraph; claims 5, 6, 12, 14, 15, 18, 25, 37, 39, 40, 42, and 47 were rejected under 35 U.S.C. § 102(b); and claims 5-9, 14, 15, 18, 25, 37-40, 42, and 45-47 were rejected for obviousness-type double patenting. Each of the rejections is addressed as follows.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 25, 37-40, 42, and 45-47 were rejected under 35 U.S.C. § 112, first paragraph. This rejection was withdrawn with respect to other, prior rejected claims, but maintained with respect to these claims, on the basis that independent claim 25 recites the term "antigen." The prior amendment to claim 5 was effective in overcoming this rejection with respect to that claim and, thus, a similar amendment is now made with respect to claim 25. Thus, claim 25 has now been amended to specify that the antigen is a polypeptide antigen. In view of this amendment, Applicants request that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 5, 6, 12, 14, 15, 18, 25, 37, 39, 40, 42, and 47 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/31235, in light of the English version, U.S. Patent No. 6,126,938. This rejection is maintained on the basis that administration to the dorsolumbar region is included in the scope of the present claims, which specify administration by the

subdiaphragmatic, systemic route. Applicants respectfully request that this rejection be withdrawn.

First, Applicants note that claim 5, from which claims 6, 10, 12, 14, 15, and 18 depend, specifies that the method "consists essentially of subdiaphragmatic, systemic administration," thus excluding the use of additional administration routes in the method. The cited reference describes the use of dorsolumbar administration in the context of a method requiring also nasal and/or buccal administration (column 4, lines 60-65) and administration by an additional mucosal route (column 4, line 66 - column 5, line 7). Thus, the cited reference does not describe the invention of claims 5, 6, 10, 12, 14, 15, and 18, and the rejection should be withdrawn with respect to these claims.

With respect to claim 25, which specifies administration by mucosal administration, followed by parenteral administration, this rejection has been maintained on the basis that the cited reference teaches administration according to the following pattern: parenteral/mucosal/parenteral/mucosal, which includes mucosal prior to parenteral. To address this rejection, claim 25 has been amended to specify that the first administration to the patient is by mucosal administration to prime an immune response, and the second administration is parenteral, to boost the immune response. Support for this amendment can be found, for example, on page 20, lines 1-3. The amendment thus makes clear that the first immunization step in the claimed method involves mucosal administration, and the cited reference does not teach mucosal administration as a first step. Applicants thus request that this rejection be withdrawn.

Further in this rejection, the Examiner notes that the cited reference teaches administration by the vaginal or rectal routes, and refers to these as subdiaphragmatic, systemic

routes. In response, Applicants note that vaginal and rectal administrations are mucosal routes, and not a systemic route, as required by the present claims. Applicants thus request that this rejection be withdrawn.

Claim 5 was rejected under 35 U.S.C. § 102(b) as being anticipated by Chen (1993), on the basis that Chen teaches "intraperitoneal" administration of Helicobacter antigens. Claim 5, as amended, requires the induction of a prophylactically effective immune response against *Helicobacter pylori*. Chen does not teach the induction of such a response. In particular, Chen does not show that the induced immune response is effective against *H. pylori*, as the model of Chen employed an *H. felis* challenge. Applicants thus request that this rejection be withdrawn.

Claim 5 was rejected under 35 U.S.C. § 102(b) as being anticipated by Fulginiti (1995), on the basis that Fulginiti teaches "intraperitoneal" administration of Helicobacter antigens. Claim 5 requires the induction of a prophylactically effective immune response against *Helicobacter pylori*. Fulginiti does not show whether the immune response induced by their approach is effective against any challenge, let alone a challenge by *H. pylori*. Applicants thus request that this rejection be withdrawn.

Claim 5 was also rejected under 35 U.S.C. § 102(b) as being anticipated by Fulginiti (1995), on the basis that Fulginiti teaches "intragastric" administration of Helicobacter antigens. In response, Applicants note that claim 5 requires administration by a subdiaphragmatic, systemic route. In contrast, the intragastric administration by Fulginiti is a mucosal approach, which was not even demonstrated to be prophylactically effective. Applicants thus request that this rejection be withdrawn.

Claims 5 and 6 were rejected under 35 U.S.C. § 102(e) as being anticipated by Michetti et al., U.S. Patent No. 6,290,962, in light of Guy (1997). This rejection is based in part on

Michetti's teaching of rectal administration of a Helicobacter antigen, and a composition including a saponin adjuvant, which the Examiner states would inherently induce a Th-1 type immune response, based on the teachings of Guy. Applicants request that this rejection be withdrawn. Claims 5 and 6 require administration by a subdiaphragmatic, systemic route. In contrast to this, Michetti uses a rectal administration approach, which is mucosal. Applicants thus request that this rejection be withdrawn.

Double Patenting

Claims 5-9, 14, 15, 18, 25, 37-40, 42, and 45-47 were rejected for obviousness-type double patenting over claims 1-28 of U.S. Patent No. 6,126,938. Applicants respectfully request that this rejection be withdrawn. As is noted above, claim 5 specifies that the claimed method consists essentially of the indicated administration step. In contrast, claim 1, the only independent claim of the '938 patent requires multiple administration steps. In addition, the other independent claim of the present application, claim 25, requires a mucosal prime followed by a parenteral boost. Claim 1 of the '938 patent requires two different mucosal administrations (nasal or buccal, and mucosal route other than nasal). In view of these differences, Applicants request that this rejection be withdrawn.

Claims 5-8 and 18 were rejected for obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,576,244. The claims of the '244 patent require administration by injection of an *H. pylori* polypeptide and a particular adjuvant (i.e., an adjuvant comprising the heat-labile toxin of *E. coli*, the B subunit thereof, cholera toxin, or the B subunit thereof). These claims make no mention of administration by subdiaphragmatic, systemic routes, as required by the present claims. In addition, the present claims do not require use of the adjuvants listed in the

claims of the '244 patent. In view of these differences, Applicants request that this rejection be withdrawn.

Claim 5 was rejected for obviousness-type double patenting over claims 1, 13, 15, and 18 of U.S. Patent No. 6,379,675. The claims of the '675 patent require the administration of Osp antigens, which are *B. burgdorferi* lipoproteins, in contrast to the *H. pylori* polypeptide antigens of the present claims. The claims also require the enhancement of an immunological response to an OspC antigen. In view of these differences, Applicants request that this rejection be withdrawn.

Claims 25, 37-40, 42, and 46 were rejected for obviousness-type double patenting over claims 1-4 and 6-15 of U.S. Patent No. 6,585,975. The claims of the '975 patent require mucosal administration of a Salmonella including a nucleic acid encoding a Helicobacter antigen, in contrast to mucosal administration of an *H. pylori* polypeptide, as is required by the present claims. In view of these differences, Applicants request that this rejection be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges not covered or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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